

## REMARKS

Entry of the above amendments and reconsideration of this application are requested. In view of the amendments and the following remarks, it is believed that all rejections have been overcome and that this application is in condition for allowance.

### *Status of All of the Claims*

Upon entry of the amendments, the status of the claims in the application will be as follows:

1. Claims 27-54, 64-66 and 68-70 will be pending and under consideration.
2. Claims 1-26, 55-63 and 67 will have been cancelled.

Claims 27-54 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Badylak et al. (U.S. Patent No. 5,695,998) in view of O'Leary (U.S. Patent No. 5,298, 222) or Kemp (U.S. Patent No. 5,460,962). This rejection is respectfully traversed for the following reasons.

The Examiner contends that Badylak '998 teaches the whole subject matter of claim 27 except for the order in which the

"treating" and "removing" steps are carried out, and that either Kemp or O'Leary provides this missing limitation.

Claim 27 now requires that the collagen-based matrix be removed from a disinfected submucosa tissue source, wherein the disinfected tissue source includes attached tunica muscularis tissue.

This aspect of the claims is not taught by Kemp, which teaches only that prior to any treatment with a disinfecting agent, the small intestine is "trimmed into a sheet, mechanically stripped and cleaned so that the tunica submucosa is [was] delaminated and separated." (See Column 4, line 61 extending over to Column 5, line 31).

Kemp does not provide the missing limitation that would have taught or suggested modification of the Badylak '998 process to arrive at the invention of claim 27. In fact, Kemp would have directed the skilled artisan squarely away from the subject matter of claim 27, because it only would have suggested treating the tissue source of Badylak with a disinfecting agent after the delamination step of Badylak. In this way, Kemp endorses what Badylak already teaches. There is no suggestion to contact the intestinal tissue of Kemp with a disinfecting agent before the trimming, mechanical stripping, etc.

O'Leary also fails to provide anything that would have taught or suggested modification of the Badylak '998 process to arrive at the invention of claim 27. O'Leary stresses the importance of carrying out its process under sterile conditions. However, O'Leary does not teach treating something with a disinfecting agent as claimed.

As a further distinction, O'Leary's main embodiment involves bone, which does not include attached tunica muscularis tissue, and is not a submucosa tissue source. During processing, connective tissue and periosteum are removed from the bone, and the bone is shaped into a specific size. Only later is the bone treated with a disinfectant. Thus, O'Leary does not provide the missing limitation that would have taught or suggested modification of the Badylak '998 process to arrive at the invention of claim 27.

For at least these reasons, claim 27 is not rendered obvious by Badylak '998 in view of O'Leary or Kemp. Claims 28-44, being dependent upon claim 27, also are not rendered obvious by the cited art for at least these reasons.

Independent claim 45 now requires that the collagen-based matrix be removed from a submucosa tissue source that (a) includes attached tunica muscularis tissue; and (b) has been treated with a disinfecting agent. In Kemp, tunica submucosa is

never removed from a tissue source that satisfies both (a) and (b). A similar rationale can be adapted and applied to O'Leary based on the information provided above, and thus none of claims 45-54 are rendered obvious by Badylak '998 in view of O'Leary or Kemp. Withdrawal of the rejection as applied to claim 45 and its dependent claims is thus also solicited.

Claims 64-66 stand rejected under 35 U.S.C. §102(e) as being anticipated by Badylak et al. '998 or Abraham et al. '844, or in the alternative, under 35 U.S.C. §103(a) as obvious over Badylak et al. '998 or Abraham '844 in view of O'Leary '222 or Kemp '962. However, independent claim 64 has now been amended to incorporate the limitation of prior claim 67. This rejection has thereby been rendered moot without admission.

Claim 67 as prior pending was rejected under 35 U.S.C. §103(a) as being unpatentable over Abraham, Badylak '98, O'Leary and Kemp in view of Badylak (U.S. Patent No. 5,554,389). To the extent that this rejection is applied to claim 64 as amended, it is submitted that it would be in error.

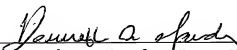
Independent claim 64 requires a combination of a remarkably high level of purification of undesired components (endotoxin level less than 1 EU/gram and bioburden level less than 0.5 CFU/gram) and retention of native beneficial components from the tissue source -- glycosaminoglycans, glycoproteins,

proteoglycans and growth factors, wherein the growth factors include basic fibroblast growth factor. These latter components beneficially contribute to the desired bioactivity of the matrix. The combination of Abraham, Badylak '98, O'Leary and Kemp in view of Badylak '389 fails to lead one of ordinary skill in the art to this claimed combination or to provide any expectation of success that it could be achieved. Accordingly, withdrawal of the subject rejection is requested.

New claims 68-70 have been added. Claim 68 is a product by process claim upon claim 64. Claim 69 is a product claim wherein the product has the combination of features defined in method claims 64 and prior 67, and finds support as previously described. Claim 70 claims a use (dermal wound treatment) of the product of claim 69, and finds support at page 24, lines 24-25. Consideration of these new claims, in which the claimed product is consistent with that defined in method claim 64, is requested. These claims are believed to be allowable at least for the reasons similar to those discussed immediately above, in that they require the claimed collagen-containing matrix with a combination of very high purity while retaining beneficial bioactive components of the original source tissue.

In view of the foregoing amendments and remarks,  
reconsideration and allowance of this application containing  
claims 27-54, 64-66 and 68-70 is requested.

Respectfully submitted,

By   
Kenneth A. Gandy, Reg. No. 33,386  
Woodard, Emhardt, Moriarty,  
McNett & Henry LLP  
111 Monument Circle, Suite 3700  
Indianapolis, Indiana 46204-5137  
Tel. (317) 634-3456  
Fax (317) 637-7561  
kgandy@uspatent.com